K112312

Attachment H

JAN 2 5 2012

PHOENIX
MEDICAL DEVICES

510(k) Summary for the Theratrode Family of Cutaneous Electrodes

1. **Sponsor**

Phoenix Medical Devices, LLC
2458 Alton Parkway
Irvine, Ca 92606

Registration Number: 3004620982

Contact Person: Jim Klett
Telephone: (800) 689-9892
Fax: (949) 266-8126

Date Prepared: February 26, 2011

2. **Device Name**

Theratrode Brand Cutaneous Electrodes comprised of the following model numbers and descriptions:

T1 = 2" (5 0.5mm) Square Electrode ("Squircle")
T2 = 2" (5cm) Round Electrode
T3 = 2" x 4" (5cm x 10cm) Rectangu lar Electrode
T4 = 2" x 4" (5cm x 10cm) Oval Electrode
T5 = 1.25" (3cm) Round Electrode
T6 = 2.75" (7cm) Round Electrode
T7 = 1.5" (4cm) Square Electrode
T8 = 1.5" x 2.5" (4cm x 6cm) Rectangular Electrode
T9 = 1.5" x 2.5" (4cm x 6cm) Oval Electrode
T10= 1.5" x 3.5" (4cm x 9cm) Rectangular Electrode
T11= 3" x 5" (7.5cm x 13cm) Rectangular Electrode
T12= 2" (5 0mm) Square Electrode

Common/Usual Name: Cutaneous Electrode
Classification Names: Electrode, Cutaneous
Classification Panel: Neurology
Panel/Product Code: 882.1320 / GXY

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3. Legally Marketed Device to Which Equivalence is Claimed
Marketed Device #1

Proprietary Name: Lifecare Electrodes, K083302

Common/Usual Name: Lifecare Neurostimulation Electrodes

Classification Names: Electrode, Cutaneous

Classification Panel: Neurology

Panel/Product Code: Neurology / GXY

4. Intended Use / Indications For Use

To conduct electrical stimulation from commercially available nerve stimulation devices to the patient's skin.

Single patient use – re-usable.

Self adhering and re-positionable.

Over the counter use.

5. Device Description

Theratrode electrodes are constructed as a layered assembly comprised of four components:

- A patient contacting layer of hydrogel material which has been tested and found to be bio-compatible with humans and provides both the electrically conductive medium necessary to aid in the transmission of electrical current to the patient plus the adhesive properties necessary to maintain sufficient contact with the patient's skin,
- A carbon dispersion pad middle layer that evenly distributes the electrical current across the surface of the electrode,
- A non-conductive top layer of various materials such as spun lace (fabric), polyethylene or polypropylene foam or other similar materials that form a protective and flexible top layer to the electrode,
- A wire or conductive carbon fiber lead wire which is glued to the assembly of the middle and top layer and terminates in a .080" (2mm) female connector common to the electrotherapy industry and which mates with the plurality of commercially available nerve stimulation devices on the market today. The female connector complies with IEC60601-1 Sub clause 56 3(c).

Theratrode electrodes are non-sterile and are intended for multiple use by a single patient to apply electrical stimulation. Theratrode's construction is equivalent to the predicate device's construction.

6. Basis for Substantial Equivalence

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We have examined the Theratrode electrodes in comparison to the Predicate Device and determined the Theratrode electrodes to be Substantially Equivalent to the Predicate Device because they both:

- Are constructed in the same manner,
- are constructed of same or similar materials,
- have identical indications for use, and
- have very similar performance characteristics (see bench test data included in this submission).

Any minor visual, dimensional or labeling differences between the Predicate device and the Theratrode electrodes do not pose any risk to their safe and effective use.

7. **Differences between the Marketed Device and the Theratrode family of cutaneous electrodes.**
There are no significant differences between the Theratrode Electrodes and the Marketed device.

8. **Bench Testing (non-clinical)**
Comparison testing was performed between the Predicate Device and the Theratrode Electrode. There are no established performance standards for cutaneous electrodes so we chose to measure the electrical conductivity (inverse of impedance) as an appropriate measure of the electrode's performance. The comparison tests conclusively prove that Theratrode is at a minimum as efficient at conducting electricity as the Predicate device.

Theratrode's hydrogel has passed three biocompatibility tests; skin irritation, cytotoxicity and delayed contact sensitization

9. **Conclusion**
Through careful examination of the construction, materials, indications for use and performance we conclude the Theratrode electrodes are Substantially Equivalent to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Phoenix Medical Devices, LLC
c/o Mr. Jim Klett
President
2458 Alton Parkway
Irvine, CA 92606

JAN 25 2012

Re: K112312
Trade/Device Name: Theratrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated: November 23, 2011
Received: November 29, 2011

Dear Mr. Klett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah Fells

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112312

Device Name: Theratrode

Model Numbers:

T1 = 2" (50.5mm) Square Electrode (Squircle Shape)
T2 = 2" (5cm) Round Electrode
T3 = 2" x 4" (5cm x 10cm) Rectangular Electrode
T4 = 2" x 4" (5cm x 10cm) Oval Electrode
T5 = 1.25" (3cm) Round Electrode
T6 = 2.75" (7cm) Round Electrode
T7 = 1.5" (4cm) Square Electrode
T8 = 1.5" x 2.5" (4cm x 6cm) Rectangular Electrode
T9 = 1.5" x 2.5" (4cm x 6cm) Oval Electrode
T10= 1.5" x 3.5" (4cm x 9cm) Rectangular Electrode
T11= 3" x 5" (7.5cm x 13cm) Rectangular Electrode
T12 = 2" (50mm) Square Electrode

Indications for Use:

To conduct electrical stimulation from common varieties of electrical stimulators to the patients skin.

Single patient use – re-usable.

Self adhering and re-positionable.

Over the counter use.

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112312

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